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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/925,796 | 08/09/2001 | Casey C. Case | 8325-0007.01 | 5123 |
| 23419 | 7590 | 12/09/2003 | EXAMINER | |
| COOLEY GODWARD, LLP 3000 EL CAMINO REAL 5 PALO ALTO SQUARE PALO ALTO, CA 94306 | | | BRUSCA, JOHN S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/925,796 | CASE ET AL. | |
| | Examiner | Art Unit | |
| | John S. Brusca | 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 October 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,5,6,8-19,24-33 and 87-113 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,8-12,14-16,87,90,92-94,96,97,102,104 and 106 is/are rejected.
- 7) Claim(s) 5,6,13,17-19,24-33,88,89,91,95,98-101,103,105 and 107-113 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 09 August 2001 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10/17/03. 6) Other: _____.

DETAILED ACTION

Specification

1. The objection to the specification for failure to comply with the sequence rules in the Office action mailed 13 August 2003 is withdrawn in view of the amendment filed 09 October 2003.

Terminal Disclaimer

2. The terminal disclaimer filed on 09 October 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S>Patent No. 6,599,692 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Inventorship

3. In view of the papers filed 07 October 2002, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48a. The inventorship of this application has been changed by addition of Fyodor Urnov.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 112

4. The rejection of claims 1, 2, 5, 6, 8-20, 24-28, 30, and 87-113 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of delivery of zinc finger proteins to cells by introduction of an expression vector, does not reasonably provide enablement for methods of delivery of zinc finger proteins to cells by introduction of exogenous zinc finger

proteins to cells in the Office action mailed 13 August 2003 is withdrawn in view of the amendment filed 09 October 2003.

5. The rejection of claims 22, 23, 26, 28, 29, 32, and 33 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in the Office action mailed 13 August 2003 is withdrawn in view of the amendment filed 09 October 2003.

Double Patenting

6. The rejection of claims 1, 2, 5, 6, 8-33, 87, 88, and 90 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5, 8-10, 12-22, 26, 27, 32, 39-41, and 55 of U.S. Patent No. 6,599,692 in the Office action mailed 13 August 2003 is withdrawn in view of the terminal disclaimer filed 09 October 2003.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would be obvious over, the reference claim(s). see, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

8. Claims 1, 2, 8-12, 14-16, 87, 90, 92-94, 96, 97, 102, 104, 106 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9, 11, 13, 14, 18-22, 23, and 26 of copending Application No. 09/942,090. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to use genes not operably linked to heterologous sequences because such species covered by the copending generic claims are disclosed in page 15, lines 21-28 of the specification of copending Application No. 09/942,090, in which guidance is provided to use endogenous target genes. It would be further obvious to use a negative control of a zinc finger that binds to a second gene because such controls covered by the copending generic claims are disclosed in page 10, lines 12-24 of the specification of copending Application No. 09/942,090, in which use of additional zinc finger proteins directed to control target genes are shown to be useful as controls.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1, 9, 10-12, 14-16, 87, and 92 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 9, 11, and 13-22 of copending Application No. 09/941450. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to use genes not operably linked to heterologous sequences because such species covered by the copending generic claims are disclosed in page 15, lines 19-26 of the specification of copending Application No. 09/941,450, in which guidance is provided to use endogenous target genes. It would be further obvious to use a negative control of a zinc finger that binds to a second gene because such controls covered by the copending generic claims are disclosed in page 10, lines 11-23 of the specification of copending Application No. 09/941,450, in which use of additional zinc finger proteins directed to control target genes are shown to be useful as controls.

10. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

11. Applicant's arguments filed 09 October 2003 have been fully considered but they are not persuasive. The applicants state that the instant claims are drawn to a method of establishing an association between a known gene and a selected phenotype while the cited copending claims are drawn to methods of identifying genes. However the instant claims recite steps of selecting genes, modulating their expression with a zinc finger protein, and determining the resulting phenotype. The copending claims are drawn to the same steps. Although the applicants point to

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the limitation in the copending claims that a **putative** gene is used, while the instant claims use genes, the difference is not sufficient to overcome the rejections because putative genes include the genes of the instant claims. The applicants state that they cannot locate the cited portions of the copending specifications that describe the instant claimed species of the copending generic claims. The rejections in the Office action mailed 13 August 2003 pointed to paragraph numbers of the corresponding U.S. publications because the text of the applications was unavailable at the time of mailing of the previous Office action. The rejections have been rewritten to point to the section of the copending applications. The applicants note correctly that the Office action mailed 13 August 2003 contained an error in that the rejection over copending application No. 09/941,450 listed a different application number in the text of the rejection. The Office apologized for any inconvenience this may have caused the applicants. The rejection has been rewritten to cite the correct passages of copending application No. 09/941,450. It is apparent from the applicants comments filed 09 October 2003 that the rejection was understood by the applicants to be based on application No. 09/941,450. Regarding use of the specification of a patent in an obviousness-type double patenting rejection, the MPEP states in section 804:

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized “that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim,” but that one can judge whether or not the invention claimed

in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first “determine how much of the patent disclosure pertains to the invention claimed in the patent” because only “[t]his portion of the specification supports the patent claims and may be considered.” The court pointed out that “this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined.”

In the instant rejections, the portions of the copending specifications pointed to in the rejections discuss types of target genes and use of controls for the copending generic method claims, and therefore discuss embodiments of the copending claimed methods. Because the copending claims are drawn to common subject matter with the instant claims, and the specifications of the copending applications discuss the species claimed in the instant application, the use of the copending specifications to support the obviousness-type double patenting rejections is proper.

Allowable Subject Matter

12. Claims 5, 6, 13, 17-19, 24-33, 88, 89, 91, 95, 98-101, 103, 105, and 107-113 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

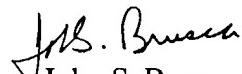
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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4028. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.


John S. Brusca
Primary Examiner
Art Unit 1631

jsb